

### **REMARKS**

The Applicants thank the Examiner for the thorough consideration given the present application. Claim 14, and 18-27 are cancelled herein without prejudice to or disclaimer of the subject matter contained therein. Claims 10-13 and 15-17, and 28-41 are pending. Claims 10 and 14 are amended. Claims 28-41 are added. Claims 10, 31, and 37 are independent. The Examiner is respectfully requested to reconsider the rejections in view of the amendments and remarks set forth herein.

### **Allowable Subject Matter**

The Examiner states that claims 14 and 15 would be allowable if rewritten in independent form.

Applicants thank the Examiner for the early indication of allowable subject matter in this application. In response, independent claim 10 has been amended to incorporate the allowable subject matter of objected-to claim 14.

Therefore, claims 10-13, 15-17 and 28-30 are now in condition for allowance.

### **Examiner Interview**

If, during further examination of the present application, any further discussion with the Applicants' Representative would advance the prosecution of the present application, the Examiner is encouraged to contact Carl T. Thomsen, at 1-703-208-4030 (direct line) at his convenience.

**Drawings**

It is gratefully appreciated that the Examiner has indicated that the drawings have been accepted.

**Claim for Priority**

It is gratefully appreciated that the Examiner has acknowledged the Applicants' claim for foreign priority.

**Information Disclosure Citation**

The Applicants thank the Examiner for considering the reference supplied with the Information Disclosure Statements filed May 4, 2005 and May 9, 2008, and for providing the Applicants with initialed copies of the PTO/SB/08 forms filed therewith.

**Restriction Requirement**

The Examiner has made the Restriction Requirement final, and has withdrawn claims 18-27 from further consideration.

**Rejections Under 35 U.S.C. §102(b) and 103(a)**

Claims 10 and 16 stand rejected under 35 U.S.C. §102(b) as being anticipated by Mileaf et al. (U.S. 5,652,149);

Claims 10-13 and 16 stand rejected under 35 U.S.C. §102(b) as being anticipated by and Southgate et al. (U.S. 5,863,502);

claims 11-13 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Mileaf et al.; and

claim 17 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Southgate et al.

These rejections are respectfully traversed.

**Amendments to Independent Claim 10**

As noted above, and while not conceding the appropriateness of the Examiner's rejection, but merely to advance prosecution of the present application, independent claim 10 has been amended to incorporate the allowable subject matter of objected-to claim 14.

In contrast to the present invention neither one of the Mileaf et al. and Southgate et al. documents discloses a slide valve as recited in independent claim 10, as amended herein.

At least for the reasons explained above, the Applicants respectfully submit that the combination of elements as set forth in independent claim 10 is not disclosed or made obvious by the prior art of record.

Therefore, independent claim 10 is in condition for allowance.

Three new dependent claims, namely dependent claims 28-30, have been added to further define the slide valve. Support for these claims can be found in paragraphs [0046], [0047] and [0051] of the publication. Therefore, all claims depending from independent claim 10, namely claims 11-13, 15-17 and 28-30, are now in condition for allowance.

**Added Independent Claim 31**

Antecedent basis for added independent 31 can be found in paragraphs [0046], [0047], and [0051] of Publication No. U.S. 2006/0013740 A1.

The Applicants submit that added independent claim 31 includes the allowable subject matter as indicated by the Examiner. In addition, dependent claims 32-36 have been added to depend from independent claim 31.

Accordingly, independent claim 31 and its dependent claims are also in condition for allowance.

**Added Independent Claim 37**

Claims 10 and 16 stand rejected 35 USC §102(b) as being anticipated by Mileaf et al. (U.S. 5,652,149). This rejection has been traversed.

Antecedent basis for added independent claim 37 can be found in paragraphs [0038], [0047], and [0049] of Publication No. U.S. 2006/0013740 A1.

With regard to new independent claim 37, Applicants submit that the claimed subject matter is not disclosed, taught or suggested by the art of record.

As positively recited in the new independent claim 37, Applicants' claimed disposable cartridge requires a valve comprising at least one valve channel having a defined volume, said valve disposed within said housing among said channels adapted to interconnect selected channels between selected receptacles for directing flow between selected receptacles through said valve channel, wherein said valve displaces a sample with

said defined volume entrapped in said at least one valve channel into selected channels between selected receptacles.

Mileaf et al. fail to teach a cartridge including a valve that comprises a valve channel having a defined volume, and further fail to teach that the valve displaces a sample with said defined volume entrapped in the valve channel into selected channels between selected receptacles.

More specifically, Mileaf et al. teach an assay device that includes multiple resilient storage reservoirs containing reagents fluidly connected to a track containing the sample. This assay device comprises a means 52 for preventing the reagents from leaking from the reservoirs 16 due to jarring or dropping of the device. Means 52 includes an elevated barrier 54 with a flat top 58 and a deflectable yielding member 56, as a portion of the flexible member 36 which is heat sealed on the surface 34 of card 30. The yielding member 56 deflects under pressure and allows fluid flows over the top 58 (see Column 5, line 54 to Column 6, line 16, and Figs. 3 and 4).

As a valve, means 52 does not have a channel having a defined volume for displacing a defined volume of a sample. Instead, because of the deflectable nature of yield member 56, this type of valve is not suitable, and is not intended, to deliver a fluid sample in a quantitative manner.

Therefore, the Mileaf et al. reference fails to anticipate or suggest Applicants' claimed invention as defined in new independent Claim 37.

With regard to added dependent claims 38-41, these claims are dependent upon

independent claim 37. Since independent claim 37 is not anticipated by the prior art of record, dependent claims 38-41 are also allowable over the art of record.

Accordingly, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. §102(b) based on Mileaf et al.

Claims 10-13 and 16 stand rejected 35 USC §102(b) as being anticipated by Southgate et al (US 5,863,502). This rejection has been traversed.

With regard to new independent claim 37, Applicants submit that the claimed subject matter is not disclosed, taught or suggested by the art of record.

More specifically, Southgate et al. fail to teach a cartridge including a valve that comprises a valve channel having a defined volume, and further fail to teach that the valve displaces a sample with said defined volume entrapped in the valve channel into selected channels between selected receptacles.

Southgate et al. merely teach a parallel reaction cassette, which comprises chambers connected serially by fluid exchange channels and a valve means 180 between the reaction chamber 160 and the waste chamber 170 (Fig. 1). As shown in Figs. 5A-7 and described in Column 16, lines 52-67, plunger valve 180 includes a seat 181 and an embossed film 110C, which permits fluid flowing from alpha fluid exchange channel 143A to beta fluid exchange channel 143B. When film 110C is pressed down on to seat 181 by a plunger, valve 180 blocks the flow. It is further noted that as can be seen from Figs. 1B, 1C, 5A, 5B and 6, the

lower side of fluid exchange channel 143A is also sealed by a film (lower film 121), and the channel extends along the film to connect to the reaction chamber.

Southgate et al. further teach several alternative embodiments, such as ball valve and electromagnetic valve shown in Figs. 8A-9B, however, all of them rely on the flexible nature of the film to start or stop the fluid communication. Moreover, similar to the embodiment shown in Figs. 5A-7, at the opposing side of the valve film, the fluid exchange channel in Figs. 9A-9B or hole 632 in Figs. 8A-8B is also sealed with a film, and the channel or hole extends along the film to connect to the reaction chamber.

Therefore, Southgate et al.'s plunger valve, ball valve or electromagnetic valve does not have a valve channel having a defined volume and is not suitable to deliver a sample with a defined volume in a quantitative manner. Further, as discussed previously, because of the flexible nature of the films, this type of valve is only used for initiating or blocking fluid communication between channels, not suitable for quantitative measurement or delivery.

Therefore, the reference fails to anticipate or suggest Applicants' claimed invention as defined in new independent claim 37. Furthermore, since added dependent claims 38-41 are dependent on independent claim 37, these claims are also allowable over the art of record.

Accordingly, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. §102(b) based on Southgate et al.

All pending claims are now in condition for allowance.

Accordingly, reconsideration and withdrawal of the rejections under 35 U.S.C. §102(b) and 103(a) are respectfully requested.

**CONCLUSION**

Since the remaining patents cited by the Examiner have not been utilized to reject claims, but merely to show the state of the art, no comment need be made with respect thereto.

All of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. It is believed that a full and complete response has been made to the outstanding Office Action, and that the present application is in condition for allowance.

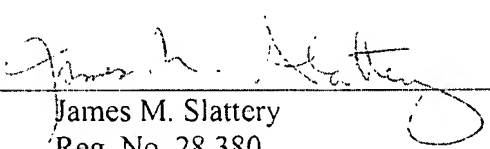
If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, he is invited to telephone Carl T. Thomsen (Reg. No. 50,786) at (703) 208-4030(direct line).

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§1.16 or 1.17, particularly extension of time fees.


Respectfully submitted,

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By

  
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